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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------|------------------|
| 10/038,835  | 01/04/2002  | Yue-Luen Bai         | I2674-006001            | 9681             |
| 26161   | 7590        | 09/01/2004           | EXAMINER                |                  |
| FISH & RICHARDSON PC<br>225 FRANKLIN ST<br>BOSTON, MA 02110 |             |                      | FREDMAN, JEFFREY NORMAN |                  |
|   |             | ART UNIT             |                         | PAPER NUMBER     |
|   |             | 1637                 |                         |                  |

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                        |                               |                            |
|------------------------|-------------------------------|----------------------------|
| <b>Advisory Action</b> | Application No.<br>10/038,835 | Applicant(s)<br>BAI ET AL. |
|                        | Examiner<br>Jeffrey Fredman   | Art Unit<br>1637           |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

THE REPLY FILED 20 August 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a)  The period for reply expires 3 months from the mailing date of the final rejection.  
 b)  The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
 ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.  A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.  
 2.  The proposed amendment(s) will not be entered because:  
 (a)  they raise new issues that would require further consideration and/or search (see NOTE below);  
 (b)  they raise the issue of new matter (see Note below);  
 (c)  they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d)  they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3.  Applicant's reply has overcome the following rejection(s): See Continuation Sheet.  
 4.  Newly proposed or amended claim(s) \_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 5.  The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.  
 6.  The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.  
 7.  For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 4,5,7,8,12,14,15 and 17.

Claim(s) withdrawn from consideration: 18-26.

8.  The drawing correction filed on \_\_\_\_ is a) approved or b) disapproved by the Examiner.

9.  Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.

10.  Other: \_\_\_\_\_.

  
 Jeffrey Fredman  
 Primary Examiner  
 Art Unit: 1637

Continuation of 3. Applicant's reply has overcome the following rejection(s): The written description rejection and the 102(b) rejection which was mooted by cancellation of claim 9..

Continuation of 5. does NOT place the application in condition for allowance because: First, with regard to the 112, second paragraph rejection, Applicant again argues a limitation in the specification. Limitations from the specification are not read into the claims. So in order to clarify this point, the claim must clearly indicate whether it is a single compound or a mixture of compounds. The claim is not so clear. The recent case of *In Re Bigio* (decided August 24, 2004) reinforces this concept, noting "In examining the term "hair brush," the Board correctly declined to import from the specification a limitation that would apply the term only to hairbrushes for the scalp." and read a toothbrush reference against the claim.

Second, with regard to the 103 rejection, Applicant argues that many different primer choices are available, so this species is an unobvious variant of the genus. In this context, however, that argument is not persuasive because every member of the genus would be expected to function and are implicit and disclosed by the prior art, in the sequence disclosure. Applicant's have not demonstrated any special properties for the claimed primer sets. So the invention simply represents selection from prior art recognized sequences of particular primers, all of which would be suitable for the claimed invention. The CAFC noted in *Deuel* that "For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties." In the present fact pattern, the expected functional equivalence of every member species of the genus of probes, suggests the homologous oligonucleotides. This suggestion, combined with the ability of a computer or scientist to completely define each and every species member solely using the prior art supports the position that each oligonucleotide is *prima facie* obvious over a prior art teaching of the entire sequence from which the oligonucleotide is derived.

While the *Duel* court did state that "The fact that one can conceive a general process in advance for preparing an undefined compound does not mean that a claimed specific compound was precisely envisioned and therefore obvious.", this is clearly distinguishable. In *Deuel*, absolutely no nucleic acid sequence was known in the prior art and the entire process and method steps cited for the rejection were devoted to isolating and sequencing unknown nucleic acids in order to identify the particular nucleic acid sequence of interest. This is in direct contrast to the current type fact pattern where, as discussed above, the entire nucleic acid sequence is known in the prior art and in oligonucleotide homologs drawn to the particular prior art sequence and target sequence are known in the prior art. Further distinguishing the oligonucleotide primer and probe situation from the situation in *Deuel* is the nearly 100% expectation of success in probe identification. So Applicant's arguments with regard to the 103 rejection are not found persuasive and this rejection is maintained.